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PROGRAMME FOR THE INDUSTRIAL PRODUCTION OF BIOLOGICALS (IPB)

Brief presentation by the UNIDO Secretariat*

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In 1977 it was estimated that less than 10% of the children born each year in the developing countries received immunization[1]. Since then the Expanded Programme on Immunization (EPI) of WHO has been progressing quickly and by the end of 1983 approximately 44% of the children born were immunized globally. This immunization coverage is less than 30% in the developing countries at present[2]. If this trend should continue the EPI will achieve its goal by 1990, that is providing immunization for all children against diphtheria,measles, poliomyelitis, tetanus, tuberculosis and whooping cough.

The higher the coverage the higher the cost of EPI. The programme required US$ 72 million in 1981 however it will cost around US$ 300 million by the end of the decade. From this figure at least one third will come from the international community by donation[3].

It is a well established fact that to control the above referred childhood diseases, immunization is the most economical solution. However to ensure that enough vaccine is available to immunize the 100 million or more children who will be born each year by 1990 and onwards, the present vaccine production and quality control capacities would need to be increased. However many participants of the 2nd Consultation on the Pharmaceutical Industry felt that there was no need to set up new production capacities for vaccines since there was ample world capacity to meet current and anticipated demand in the near future[4].

Does this mean that the developing countries, with a well established delivery system for immunization and certified quality control facilities for biologicals should be dependent indefinitely on imports and donations?

1_ Progress Report by the Director General, EPI, WHO, WHA 30, A30/13, 1977

2_ Immunization Health and Development, WHO, WPR No. 19, 1983

3_ Report of the EPI Global Advisory Group Meeting, WHO, EPI/GEN/81/12

4_ UNIDO, ID/311, p. 121, 1984

Does this mean that the present industrial capacity can cope with an increase in demand of approximately 300% without additional investment? Can the United Nations Agencies and Organisations give an assurance that the present pricing of vaccines and the donations required can also be provided after 1990 when the present demands of developing countries shall have tripled?

Or could it be envisaged that this increased demand will drop in consequence of control of at least some of the above referred diseases? If so, would it allow the deployment of resources to control some further prevalent diseases by introducing immunization with any recently developed vaccines?

Obviously WHO/UNICEF also faced the same questions and therefore already in 1977, in his Progress Report, the Director General of WHO stated and I quote:

> "UNIDO should be stimulated to take a greater interest in vaccine production in the developing world as a part of its involvement in developing the manufacture of medicine in these countries" unquote[1]

UNICEF has also taken action to develop a special support programme for primary health care so called GOBI, with low cost methods of growth monitoring, oral rehydration therapy, breast feeding and immunization.

In 1982 WHO was still preoccupied with the possible shortage of vaccines not only with regard to the EPI programmes but also the general goal of "Health for All" and therefore WHO has emphasized the need for production of vaccines in developing countries since their supplies will be critically limited in the near future[5].

Based on the above it is obvious that UNIDO has to develop its own programme for production of biologicals. Even the delayed reaction of UNIDO might be beneficial for the implementation of such a programme since the accelerated EPI programmes have already established the delivery system for vaccines in many developing countries and at the same created a market for these products. Other elements of the EPI such as establishing immunization centres, training of manage-

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5_ A compendium of WHO's collaborative activities with the United Nations System, WHO, CWO/82.2.

ment and personnel for the programme, increasing social acceptance of immunization and last but not least, establishing and certifying national or regional quality control facilities, have utmost importance. To promote regional self-reliance is also one of the long-term objectives of EPI.[6] However while the domestic vaccine production is only one of the targets of EPI, it should be the central preoccupation of UNIDO based on the recommendations of the 2nd Consultation on the Pharmaceutical Industry[7] and the increased number of requests received from developing countries for Technical Assistance in establishing production units for biologicals. UNIDO's intention is to provide developing countries with all the relevant techo-economic information for establishing industrial production of biologicals. In this regard the main elements will be the assessment and choice of available technologies giving due importance to factors such as production strains, raw materials and equipment required; the quality, reproductibility and the cost of the product; the staff and infrastructure requirements; the minimum/maximum technical and economic scale of production and the investment required. The selected technology should be suitable for the recipient country depending on its level of development and capability to assimilate it.

To fulfil this task, UNIDO would like also to clarify the methodology of implementation. Consequently it is UNIDO's aim to collect and process information, to prepare directories of supply for raw materials, biologicals and even technologies,to prepare model programmes as guidelines for developing production facilities.

However by establishing IPB, UNIDO is not aiming to reach the EPI's target percentage-wise. The EPI's main target is to achieve 100% coverage of immunization, obviously IPB does not intend to establish such an industrial capacity in developing countries which could meet the entire demand of the Third World. UNIDO's intention is only to implement case projects and through this to demonstrate that developing countries if desired can reach a relative self-reliance in biologicals upon adopting an industrial approach. In this connection co-operation with WHO/UNICEF will be of great importance and benefit to the developing countries. This co-operation will reflect the already existing co-operation between UNIDO and WHO.

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6 _ Progress Report by the Director General EPI, WHO, WHA 30 A 31/21 1978

7_ UNIDO, ID/311 p.10-12 1984

In order to achieve success in this programme, the distinguished members of the Advisory Panel are invited to advise UNIDO on the following :

(a) Establishing an illustrative list of biologicals.

(b) Identifying criteria for industrial technology for the production of biologicals by characterising its main technical and economic aspects.

(c) Sources of technology and transfer of technology.

(d) Steps to be taken concerning implementation of the IPB programme such as the carrying out of surveys for collection of information, organising Advisory Expert Group Meetings, implementing case projects at different techno-economic levels in Africa, Asia and Latin America.

(e) Co-operation among UN agencies and organisations, bilateral agreements and TCDC.

(f) Specific guidelines for implementation of the recommendations of the 2nd Consultation on the Pharmaceutical Industry.

(g) Responsibilities and committments for the implementation of the IPB.

The Secretariat trusts that this meeting will be carried out in a most cordial and co-operative atmosphere for the benefit of the developing countries.